

Remarks

Claims 31- 45 are pending in the application. Claims 31-40 stand rejected under 35 U.S.C. § 103(a). Claims 41-45 have been added. Support for the new claims can be found throughout the specification and in particular page 8, line 25 to page 9, line 7.

Interview Summary

Applicants thank the Examiner and her Supervisor for the interview conducted on May 2, 2003. Although no agreement was reached, Applicants appreciate the Examiners' comments and suggestions.

In addition to the Interview Summary Form provided at the interview on May 2, 2003, Applicants provide the following summary to comply with MPEP 713.04. Claims 31-40 were discussed. U.S. Pat. No. 5,460,833 ("Andrews"), U.S. Pat. No. 5,188,822 ("Viccaro"), and U.S. Patent No. 5,188,822 ("Carmody") were also discussed. Applicants and the Examiners discussed the teachings of Viccaro and Carmody regarding benzoic and salicylic acid as an antimicrobial agent.

Applicants also inquired about the previous rejection of the two-part system, as discussed in the final Office Action mailed January 29, 2003 and as claimed in previously canceled claims 18-22. The Examiner indicated that these claims would not be discussed and would more properly be the subject of a restriction requirement. Applicants have presented the claims as new claims 41-45 for consideration.

Rejections under 35 U.S.C. § 103

Claims 31-40 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 5,460,833 ("Andrews") in view of U.S. Pat. Nos. 5,188,822 ("Viccaro") and 5,188,822 ("Carmody"). Viccaro discloses benzoic acid for use as an antimicrobial agent in dental compositions. Carmody discloses salicylic acid as a antimicrobial agent in skin formulations. The Examiner states that "one of ordinary skill in the art would have reasonably expected that employing or adding benzoic or salicylic acid . . . in the antimicrobial composition of Andrews et al. would improve the antimicrobial effect for the composition of Andrews et al."

To establish a *prima facie* case of obviousness, three basic criteria must be met:

- 1) there must be some suggestion or motivation, either in the reference or the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings;
- 2) there must be a reasonable expectation of success;
- 3) the prior art reference, or combined references must teach or suggest all the claim limitations.

Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicants' disclosure.

First, there is no teaching or suggestion in Andrews that would have led one of ordinary skill in the art to modify the formulations of Andrews to substitute either benzoic acid or salicylic acid as an enhancer. Andrews (column 4, lines 44-56) identifies certain organic acids that may be used in the antimicrobial formulations. No general class of organic acids that includes benzoic acid or salicylic acid is identified as being suitable for use in the Andrews' formulations. The Examiner acknowledged that neither benzoic acid nor salicylic acid is among the specific organic acids identified in Andrews.

Additionally, Applicants dispute the Examiner's conclusion that antimicrobial compositions would retain the same antimicrobial activity by substituting benzoic or salicylic acid in place of those listed in Andrews as an enhancer. There is no teaching or suggestion in the cited references or in knowledge generally available to one skilled in the art that the antimicrobial activity of such compositions remains sufficient to meet its intended application regardless of the individual antimicrobial constituents. On the contrary, Andrews recites that the combination of the specific components imparts the desired antimicrobial activity.

The Examiner reasons that since "all active composition components herein are known to be useful in antimicrobial compositions, it is considered obvious to combine them into a single composition to form a third composition useful for the very same purpose." This recites at most an additive effect but provides no teaching that the combination of components, i.e., benzoic acid or salicylic acid and fatty acid monoester, would provide a "synergistic antimicrobial activity" as discussed on page 7, lines 1-2 of Applicants' Specification.

Second, there is no teaching or suggestion in Andrews that would have provided one of ordinary skill in the art a reasonable expectation of success that benzoic acid or salicylic acid would be effective as an enhancer in an antimicrobial formulation such as that described in Andrews. Benzoic and salicylic acid are known to be weak antimicrobial agents, and more commonly considered antifungal agents. See Remington's Pharmaceutical Sciences, (14th Ed. 1970). In cases where benzoic acid, or more generally sodium benzoate, has been used as preservative in food, it has been considered at most to be a bacteriostatic agent, not a bacteriocidal agent that would result in fast, effective kill of bacteria. (Andrews Affidavit, P. 6)

Based on the known information regarding benzoic and salicylic acid, it would have not been obvious that either benzoic or salicylic acid, when combined with FAME, would provide synergistic kill against gram negative bacteria. The fact that a compound has known antimicrobial effects provides no indication whether the compound will have effective synergistic effects when combined with FAME. (Andrews Affidavit, P.7)

Applicants have attached for the Examiner's consideration the results of a bacterial kill – rate test performed on oranges using three different formulations comprising benzoic acid, salicylic acid, and lactic acid respectively. The attached test results show that benzoic and salicylic acid provide improved log reduction of gram negative bacteria within two minutes when compared to the same formulation using lactic acid. Based on the known narrow spectrum of antimicrobial activity of benzoic and salicylic acid, it was an unexpected and surprising result that these acids demonstrated synergistic effects with FAME, and that these results were superior to alpha-hydroxy organic acids such as lactic acid. (Andrews Affidavit, P. 9)

Secondary References

Secondary references Viccaro and Carmody do not cure the deficiencies of Andrews for the following reasons. As an initial matter, there is no suggestion or motivation contained in any of the secondary references to combine their teachings with the Andrews reference, and the Examiner has not identified any such motivation or suggestion. Also, even were the combinations proper, each of the combined references fails to suggest the present claims.

Specifically, the Viccaro reference is directed to an oral composition for application to teeth. While Viccaro discloses benzoic acid as an antimicrobial agent that dissolves in Viccaro's formulation for reducing bacteria that produce plaque, no efficacy data is provided regarding bacteria reduction. Further, Viccaro lacks any suggestion for combining its teaching of benzoic acid with Andrews fatty acid monester formulations to accomplish synergistic kill of gram negative bacteria.

The Carmody reference is generally directed to treating skin disorders with an antimicrobial agent suspended in a hydrophobic macroporous highly crosslinked copolymer. Again, the Carmody reference fails to teach either efficacy data for salicyclic acid or its effective application in combination with fatty acid monester formulations to accomplish synergistic kill of gram negative bacteria.

Thus, none of the references can be combined (and are not properly combined) to render the present claims obvious. Applicants submit, therefore, that rejected claims 31-40 are patentable under 35 U.S.C. § 103(a), and respectfully request that the rejections be withdrawn.

CONCLUSION

In view of the amendments and remarks provided above, Applicants submit that all claims under consideration are in condition for allowance. Examination and allowance of the claims is respectfully requested.

Respectfully submitted,

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